REMARKS

Claims 1, 3, 4, 7-38, 40, 41, 44-80, 82, and 84-94 are pending. Claims 38, 40, 41, 44-80, and 82 are withdrawn as being directed to a non-elected invention. Claims 1, 3, 4, 7-37, and 84-94 are rejected under 35 U.S.C. § 112, first paragraph, for lack of written description (new matter). By this reply, Applicants amend the specification, amend claims 1, 3, 4, 7, 8, 9, 10, 37, 38, 40, 41, 44-47, 77, 78, and 80, add new claims 95-105, request rejoinder of claims 38, 40, 41, 44-80, and 82, and address each of the Examiner's rejections.

Telephone Interview with the Examiner

Applicants wish to thank Examiner Azpuru for the courtesy of a telephonic interview on May 19, 2009, during which the present rejection was discussed. Examiner Azpuru stated that a final review of the claims, as presently amended, would be required, but acknowledged that the present claims were likely in condition for allowance.

Support for the Amendment

Support for the amendment to the specification is found in original claims 2-10, 18-22, and 36. Support for the amendment to claims 1, 3, 4, 7, 8, 9, 10, 37, 38, 40, 41, 44-47, 77, 78, and 80 is found in the specification at, e.g., page 11, lines 8-15, and in Table 2 on page 44. Support for new claims 95-105 is found in the specification at, e.g., page 12, lines 5-20. No new matter is added by the amendment.

Rejoinder

Claims 38, 40, 41, 44-80, and 82 are withdrawn from consideration. In response to the Restriction Requirement mailed on October 16, 2007, Applicants were required to choose between four invention groups. Applicants elected the claims of Group I directed to an osteoinductive powder. Applicants have amended withdrawn claims 38, 40, 41, 44-80, and 82 during prosecution to include the same limitations as examined claims 1, 3, 4, 7-37, and 84-94. Thus, upon the allowance of claims 1, 3, 4, 7-37, and 84-94, Applicants respectfully request reconsideration of the restriction requirement and rejoinder and allowance of withdrawn claims 38, 40, 41, 44-80, and 82 (see M.P.E.P. § 821.04).

Rejections under 35 U.S.C. § 112, first paragraph

The Office rejects claims 3, 4, 7-10, 15, 18-22, 33, and 36 under 35 U.S.C. § 112, first paragraph, for new matter, stating that "applicant should amend the specification to reflect the same values set out in the claims in order to make the specification and claims commensurate. Doing so will remove the rejection under 35 U.S.C. 112, first paragraph for written description" (Office Action, p. 2). As suggested by the Office, Applicants have amended the specification to include the subject matter of original claims 2-10 and 18-22. Applicants note that the subject matter of present claims 33 and 15 is found in the present specification at, e.g., page 6, lines 16-19, and page 13, lines 9-12, respectively. Applicants respectfully request that this rejection be withdrawn.

During the telephonic interview of May 19, 2009, the Examiner acknowledged that the amendment to the specification fully addressed this rejection and that it would be withdrawn.

The Office also rejects claims 1, 3, 4, 7-37, and 84-94 under 35 U.S.C. § 112, first paragraph, for new matter, stating that "Applicant has amended the claims to include concentration ranges which are not specifically set out in the originally filed specification. As such, they are considered new matter" (Office Action, p. 3). Applicants respectfully disagree.

There is no *per se* rule that ranges in claims must correspond exactly with those disclosed in the specification; the "issue is whether one skilled in the art could derive the claimed ranges" from the disclosure provided. *See Vas-Cath v. Mahurkar*, 935 F.2d 1555, 1566 (Fed. Cir. 1991) (citing *Ralston Purina v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985). An applicant "need not be bound to maximum precision for [a claimed range] when the whole tenor of his disclosure indicates approximation." *Eiselstein v. Frank*, 52 F.3d 1035, 1040 (Fed. Cir. 1995).

See also, e.g., M.P.E.P. § 2163.05(III) ("With respect to changing numerical range limitations, the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure.") and *Ex parte Noelle*, Appeal No. 2008-0011 (Bd. Pat. App. & Inter. 2008) (reversing the Office's written description rejection of claim 7 and finding written description support for the range of 6 to 10 days from a specification that disclosed "about 1-2 days to 30 days, more typically about 5-15 days, and most typically about 10 days"); *Ex parte Belardelli*, Appeal No. 2008-1869 (Bd. Pat. App. & Inter. 2008) (reversing the Office's written description rejection of claims having the limitation of specific growth factors at a concentration in a range of 500-1,000 IU/ml based on support in the specification of multiple overlapping concentration ranges).

Here, one of skill in the art could easily derive the claimed ranges from the description

provided in Applicants' specification. For example, as was discussed during the telephonic interview of May 19, 2009, support for the concentration range for DBM of 40 to 70 wt% is found in the specification at, e.g., page 11, lines 8-15 ("the DBM in the bone implant materials is present in an amount between about 10 and about 70 weight percent of the powder component") and in Table 2 on page 44, which describes formulations for several compositions in which DBM is present in a range from 40 wt% to 70 wt% (see, e.g., column 1 of Table 2). Applicants have also amended claims 1, 3, 4, 37, 38, 40, 41, 77, 78, and 80 to clarify that the DBM can be particles and fibers, both of which are fully described in the specification (see, e.g., Table 2, which describes compositions having DBM particles and fibers).

In addition, the specification provides support for the concentration range of the calcium phosphate powder of about 25 wt% to about 60 wt% on, e.g., page 17, line 19, through page 18, line 4 ("the calcium phosphate powder will be present in an amount between about 20 and about 90 weight percent of the powder component"), and in Table 2 on page 44, which shows formulations for several compositions in which calcium phosphate powder is present in a range from 25 wt% to 60 wt% (see, e.g., column 5 of Table 2).

Applicants respectfully request that the rejection of claims 1, 3, 4, 7-37, and 84-94 under 35 U.S.C. § 112, first paragraph, for new matter, be withdrawn.

CONCLUSION

In view of the above remarks, Applicants respectfully submit that the present claims are in condition for allowance, and such action is respectfully requested.

A petition to extend the period for replying for two months, to and including June 8, 2009, is submitted herewith. Applicant authorizes the Office to deduct the fee required by 37 C.F.R. § 1.17(a) for the petition from Deposit Account No. 03-2095.

If there are any additional charges, or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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